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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:

MCNEIL et al.

Serial No.: 10/716,163

Filed: November 17, 2003

Atty. File No.: 5009-1

For: PHARMACEUTICAL  
COMPOSITION

) Group Art Unit: 1654

) Examiner: Flood, M.

) SUPPLEMENTAL INFORMATION  
) DISCLOSURE STATEMENT

CERTIFICATE OF MAILING

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS  
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SHERIDAN ROSS P.C.

BY: *Christine Jacquet*

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

The references cited on attached Form PTO-1449 are being called to the attention of the Examiner.

☒ Copies of the cited non-patent and/or foreign references are enclosed herewith.  
☐ Copies of the cited U.S. patents and/or patent applications are enclosed herewith.  
☐ Copies of the cited U.S. patents/patent application publications are not enclosed in accordance with 37 C.F.R. § 1.98(a).

☐ Copies of the cited references are not enclosed, in accordance with 37 C.F.R. § 1.98(d), because the references were cited by or submitted to the U.S. Patent and Trademark Office in prior application Serial No. \_\_\_\_\_ filed \_\_\_\_\_, which is relied upon for an earlier filing date under 35 U.S.C. § 120.

Submission of the above information is not intended as an admission that any item is citable under the statutes or rules to support a rejection, that any item disclosed represents analogous art, or that those skilled in the art would refer to or recognize the pertinence of any reference without the benefit of hindsight, nor should an inference be drawn as to the pertinence of the references based on the order in which they are presented. Submission of this statement should not be taken as an indication that a search has been conducted, or that no better art exists.

It is respectfully requested that the cited information be expressly considered during the prosecution of this application and the references made of record therein.

### FEES

<input type="checkbox"/>	<p><b>37 CFR 1.97(b):</b> No fee is believed due in connection with this submission, because the information disclosure statement submitted herewith is satisfies one of the following conditions ("X" indicates satisfaction):</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d), or</li> <li><input type="checkbox"/> Within three months of the date of entry into the national stage of an international application as set forth in 37 CFR 1.491 or</li> <li><input type="checkbox"/> Before the mailing date of a first Office Action on the merits, or</li> <li><input type="checkbox"/> Before the mailing of a first Office action after the filing of a request for continued examination under 37 CFR 1.114.</li> </ul> <p>Although no fee is believed due, if any fee is deemed due in connection with this submission, please charge such fee to Deposit Account 19-1970.</p>
<input checked="" type="checkbox"/>	<p><b>37 CFR 1.97(c):</b> The information disclosure statement transmitted herewith is being filed after all the above conditions (37 CFR 1.97(b)), but before the mailing date of one of the following conditions:</p> <ul style="list-style-type: none"> <li>(1) a final action under 37 C.F.R. 1.113 or</li> <li>(2) a notice of allowance under 37 C.F.R. 1.311, or</li> <li>(3) an action that otherwise closes prosecution in the application.</li> </ul> <p>This Information Disclosure Statement is accompanied by:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> A Certification (below) as specified by 37 C.F.R. 1.97(e). Although no fee is believed due, if any fee is deemed due in connection with this submission, please charge such fee to Deposit Account 19-1970.</li> </ul> <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Please charge Deposit Account 19-1970 in the amount of \$180.00 for the fee set forth in 37 C.F.R. 1.17(p) for submission of an information disclosure statement. Please credit any overpayment or charge any underpayment to Deposit Account 19-1970.</li> </ul>
<input type="checkbox"/>	<p><b>37 CFR 1.97(d):</b> This Information Disclosure Statement is being submitted after the period specified in 37 CFR 1.97(c).</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> This information Disclosure Statement includes a Certification (below) as specified by 37 C.F.R. 1.97(e)</li> </ul> <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Applicants hereby requests consideration of the reference(s) disclosed herein. Please charge Deposit Account 19-1970 in the amount of \$180.00 under 37 C.F.R. 1.17(p). Please credit any overpayment or charge any underpayment to Deposit Account 19-1970. Election to pay the fee should not be taken as an indication that applicant(s) cannot execute a certification.</li> </ul>

**Certification (37 C.F.R. 1.97(e))**  
(Applicable only if checked)

☐ The undersigned certifies that:

☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement. 37 C.F.R. 1.97(e)(1).

☐ A copy of the communication from the foreign patent office is enclosed.

OR

☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement. 37 C.F.R. 1.97(e)(2).

Respectfully submitted,

SHERIDAN ROSS P.C.

By: Robert D. Traver

Robert D. Traver  
Registration No. 47,999  
1560 Broadway, Suite 1200  
Denver, Colorado 80202-5141  
(303) 863-9700

Date: 19 JAN 2006



Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT****Complete if Known**

Application Number	10/716,163
Filing Date	November 17, 2003
First Named Inventor	McNeil
Art Unit	1614
Examiner Name	Flood, M.
Attorney Docket Number	5009-1

Sheet	1	of	1
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**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee of Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> ; Number <sup>4</sup> ; Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
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**OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)**

Examiner Initials*	Cite No. <sup>1</sup>	
	AA	Adam, "A Treatment for the Acute Migraine Attack"; <u>The Journal of International Medical Research</u> ; 1987; 15: pps. 71-75.
	AB	Persaud et al.; "The relative bioavailability of paracetamol and codeine after oral administration of a combination of buclizine, paracetamol and codeine, with or without docusate, and of paracetamol alone in healthy volunteers"; <u>Current Medical Research and Opinions</u> ; Vol. 9, No. 9, 1985; pps. 626-633.
	AC	Tylox® product information page; McNeil Pharmaceutical revised June 1997.

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference is considered, whether or not citation is in conformance and not considered. Include copy of this form with next communication to applicant.